B. Dries 8/27/97 9/19/97

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
DETROIT DISTRICT

1560 E. Jefferson Avenue
Detroit, MI 48207-3179
TELEPHONE: 313-226-6260
FACSIMILE: 313-226-3076

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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER
97-DT-15

August 26, 1997

Terry Szczepanski
Branch Manager
Peninsula Health Care
1175 W. Washington
Marquette, Michigan 49855

Dear Mr. Szczepanski:

This letter will serve to confirm Compliance Officer Judith A. Putz's August 20, 1997 telephone conversation regarding Investigator Kelley Clark's July 14, 1997 inspection of your Oxygen, USP transfilling operation. The Investigator found your firm to be operating with significant deviations from the Current Good Manufacturing Practice (CGMP) regulations for drug products [Title 21, Code of Federal Regulations, Parts 210 and 211].

Oxygen USP is a drug within the meaning of Section 201(g) of the Federal Food, Drug and Cosmetic Act (The Act).

Your medical gases are adulterated within the meaning of Section 501(a)(2)(B) of the Act in that the controls used for the manufacture, processing, packaging or holding of the product are not in conformance with 21 CFR 210 and 211. Violations encountered during the FDA inspection include, but are not limited to, the following:

Failure to establish written specifications for Oxygen, USP [CFR 211.160(b)].

Failure to maintain complete records of the periodic calibration of the oxygen analyzer, [CFR 211.194(d)].

Failure to reject Oxygen USP, which failed to meet established standards [CFR211.165(f)].

Your Oxygen USP, which was transfilled on 4/18 & 21/97 and released at 98% and 98.7% purity is in violation of Section 501(b) of the Act in that Oxygen is recognized in the official compendium and its purity falls below the standards set forth in that compendium.

The above violations are not meant to be an all-inclusive list of deficiencies in your operation. It is your responsibility to assure that your firm's products adhere to the requirements of the Act and its implementing regulations. Federal agencies are advised of the issuance of all Warning Letters about drugs so that they may take this information into account when considering the award of contracts. A copy of "Compressed Medical Gases Guideline" is enclosed for your reference. The United States Pharmacopeia (U.S.P. 23) 1995 and supplements should be available at your local library.

Please notify this office in writing within 15 working days of the receipt of this letter of the specific steps you have taken to correct these violations and to prevent their recurrence. Your response should be directed to the attention of Mrs. Judith A. Putz, Compliance Officer, U.S. Food & Drug Administration, 1560 East Jefferson Ave., Detroit, MI 48207 (Telephone: 313-226-6260 ext. 137).

Sincerely yours,

John P. Dempster
for Raymond V. Mlecko
Acting District Director
Detroit District

2 Enclosures:
Fresh Air '97' - A look at FDA's Medical Gas Requirements
Compressed Medical Gases Guideline (Revised) February 1989

cc: Mr. Anthony Filippis
Wright and Filippis
2845 Crooks Road
Rochester Hills, MI 48309